REMARKS

The invention relates in part to assay devices that utilize mass transport by laminar flow of a sample through the layers of the device. Because laminar flow overcomes limitations in sensitivity caused by diffusion boundary formation as an analyte binds to a surface the devices of the present invention can provide advantageous capture efficiencies.

Claims 1-50 are currently pending in the instant application with claims 13-17 and 35 being withdrawn from consideration. Claims 1-6, 18-19 and 23 are amended herein. The amended claims are fully supported by the specification, and do not introduce new matter or require a new search. The amendments simply clarify the claimed invention using preferring terminology, and are not intended to further limit the claim, and should not be taken to do so.

Notwithstanding the foregoing, Applicants expressly reserve the right to pursue subject matter no longer claimed in the instant application in one or more applications which may claim priority hereto. Applicants respectfully request reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

Non Art-Related Remarks

35 U.S.C. § 112, Second Paragraph

Applicants respectfully traverse the rejection of claims 1, 3, 5, 7-12, 18 and 20-22 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention..

When determining definiteness, the proper standard to be applied is "whether one skilled in the art would understand the bounds of the claim when read in the light of the specification." *Credle v. Bond*, 30 USPQ2d 1911, 1919 (Fed. Cir. 1994). See also *Miles Laboratories, Inc. v. Shandon, Inc.*, 27 USPQ2d 1123, 1127 (Fed. Cir. 1993) ("If the claims read in the light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.") (emphasis added).

Applicants respectfully disagree with the contention that the phrase "through said layers," in claims 1-6 and 18-19 is allegedly unclear as to which layers the claims refer. Applicants respectfully submit that the phrase "through said layers" clearly refers to each of the layers recited in the claims. Nevertheless in an effort to advance prosecution, Applicants have amended

claims to clarify that laminar flow in the devices of the claims occurs through each of the recited layers via channels in the device. Applicants submit that the foregoing amendments render the rejection moot, and respectfully request that the rejection be withdrawn.

Art-Related Remarks

35 U.S.C. § 102

Applicants respectfully traverse the rejection of claims 18, 19, and 23 under 35 U.S.C. § 102(b) as allegedly being anticipated by Brecht *et al.*, Anal. Chim. Acta 311: 289-299 (1995).

In order to anticipate a claim, a single prior art publication must provide each and every element set forth in the claim. Furthermore, the claims must be interpreted in light of the teachings of the specification. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). *See* also MPEP §2131.

As discussed in Applicants' previous responses, the Brecht *et al.* publication does not provide any devices in which laminar flow is provided. Indeed, the Examiner's attention is directed to Paper No. 11, part 2, in which the Examiner concedes that cells disclosed in the Brecht *et al.* publication are not true "laminar flow" cells and thus do not provide laminar flow as recited in the instant claims. In contradiction to the Examiner's contention that "laminar flow is clearly disclosed" in the Brecht *et al.* publication, the mere fact that the Brecht *et al.* publication uses the words "laminar flow" is not relevant to the question of anticipation. As noted by the Court of Appeals for the Federal Circuit in *Applied Medical Resources Corp. v. United States Surgical Corp.*, 47 USPQ2d 1289, 1293 (1998):

> "[w]hile the experts may use the same words... to describe both the [claimed device] and the [prior art device], it is apparent that they are being used in different ways to connote different intended functions. The [prior art device] cannot anticipate the [claimed device] simply by possessing identically named parts, unless these parts also have the same structure or otherwise satisfy the claim limitations, and were understood to function in the same way by one skilled in the art."

Thus, unless a single prior art publication provides each and every element set forth in the claim, no *prima facie* case of anticipation is established. Because the Examiner concedes that the Brecht *et al.* publication does not disclose devices configured to provide laminar flow as required

by the instant claims, Applicants respectfully submit that the instant rejection is fatally flawed and request that the rejection be withdrawn.

Moreover, even if "laminar flow" is provided by the devices disclosed in the Brecht *et al.* publication, reagent flow in such devices does not occur through the layers of the device via channels, but rather across a device surface lacking channels, exiting at an opening in a surface of the device lacking any of the layers of the present claims. See, e.g., Brecht *et al.*, page 292, "Setup" (a "chip" comprising interference layers as mounted on a flow cell; in the "laminar" flow cell, inlet and outlet are on the sides of the cell, and no channels are present on the "chip").

Additionally, the Examiner contends that "the linker and analyte type attachment layers are well known 'not' to be flat surfaces such as a flat piece of glass but rather are made up of moieties of some length which might be visualized as blades of grass waving in a lake or river," and that, therefore, laminar flow through these layers is inherent. Paper No. 23, paragraph bridging pages 3 and 4. Applicants respectfully request that the Examiner cite objective evidence for the unsupported assertion that such a structure is an inherent feature of the layers of the devices disclosed in the Brecht *et al.* publication, and that flow through such layers is inherently laminar flow, particularly as the Examiner concedes that the Brecht *et al.* publication does not disclose laminar flow.

Moreover, Applicants note that the instant claims refer to flow through each recited layer via channels. respectfully submit that flow does not occur through such layers via channels, and that flow through the interference layers of the devices of the Brecht *et al.* publication would cause delamination of such layers from the underlying support.

Because Brecht *et al.* publication does not teach each and every element set forth in the claims, no *prima facie* case of anticipation has been established. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

35 U.S.C. §103

Applicants respectfully traverse the rejection of claims 1, 2, 5, 6, 9, 18-20, 22-24, 26 and 36 under 35 U.S.C. §103(a), as allegedly being unpatentable over Oberhardt, U.S. Patent No. 4,849,340 ("the '340 patent").

To establish a *prima facie* case of obviousness, three criteria must be met: there must be some motivation or suggestion, either in the cited publications or in knowledge available to the ordinarily skilled artisan, to modify or combine the publications; there must be a reasonable expectation of success in combining the publications; and the publications must teach or suggest all of the claim limitations. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) See also MPEP §2143.

Applicants respectfully disagree with the Examiner's contention that a variety of "optically functional layer" types are described in the '340 patent. Paper No. 23, page 5. Applicants respectfully submit that the Examiner has misinterpreted the meaning of the phrase "optically functional layer" in the instant claims. As Applicants noted previous, the "optically functional layer" defined in the instant application refers to a layer that contains the active components required to produce a signal upon analyte binding. This signal is produced by a modification of the optical properties of the surface resulting solely from binding of material to the surface, and not through the use of labeled species such as fluorescent molecules. *See*, specification page 10, lines 4-23. Applicants submit that the Examiner has failed to properly interpret this claim element in light of the teachings of the specification. *See, e.g., Hybritech Inc. v. Monoclonal Anti-bodies, Inc* ., 231 USPQ 81, 94-95 (Fed. Cir. 1986) (Claims are not interpreted in a vacuum, but are part of and are read in light of the specification).

Moreover, Applicants respectfully submit that the Examiner's discussion of the definition of the phrase "optically functional layer" (Paper No. 23, page 8, lines 10-15) considers only a small section of the instant specification, by which the Examiner draws the spurious conclusion that fluorescence or optical scattering is within the scope of the claims. Applicants respectfully submit that the Examiner's interpretation of the phrase must consider both the specification and the statements made in the file history. *See, e.g.*, MPEP § 2173.05(a) (a patentee is free to be his or her own lexicographer, so long as that meaning is made clear in the specification or file history). Applicants statements make clear that an optically functional layer, as that term is used in the present invention, refers to a surface on which a signal is produced by a modification of the optical properties of the surface, and that the modification results solely from binding of material to the surface, and not through the use of labeled species such as fluorescent molecules.

Thus, when properly interpreted, it is clear that no optically functional layer is disclosed or suggested by the '340 patent.

Furthermore, as recognized by the Examiner (Paper No. 23, page 6), the '340 patent does not disclose laminar flow through the reflective surface. While the Examiner contends that "it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to optionally construct and utilize a device with laminar flow through various layer selections because the '340 patent alleged to describe a wide variety of optically functional layers as well as supports, channels, analyte attachment layers, etc.," this unsupported assertion by the Examiner lacks a key element of any obviousness rejection -- a motivation to perform the modification suggested by the Examiner. *See, e.g., In re Kotzab*, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (to support a prima facie case of obviousness, "particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed" in order to support an obviousness rejection) (emphasis added).

As such, the Examiner's bare assertion is not sufficient to support a *prima facie* case of obviousness. *See also*, MPEP §2143.01 (The fact that references may be combined or modified does not render the combination or modification obvious unless the prior art suggests the desirability of the combination or modification; the fact that the claimed invention is within the capabilities of one skilled in the art, without some objective reason to provide the claimed invention, cannot support a *prima facie* case of obviousness). Nothing in the Examiner's alleged *prima facie* case suggests the desirability of providing any device in which laminar flow occurs through or through and across the layers of the devices disclosed in the '340 patent, as required by the instant claims.

Because the '340 patent fails to teach or suggest all of the limitations set forth in the instant claims, and because nothing in the Examiner's asserted *prima facie* case provides any motivation to modify the devices of the cited patent to provide the instantly claimed invention, , no *prima facie* case of obviousness has been established. Applicants respectfully request that the rejection under 35 U.S.C. §103 be reconsidered and withdrawn.

Applicants also respectfully traverse the rejection of claims 1, 2, 5, 6, 9, 18-20, 22-24, 26 and 36 under 35 U.S.C. §103(a), as allegedly being unpatentable over Walt *et al.*, U.S. Patent No. 6,023,540 ("the '540 patent").

The present application claims priority to U.S. Patent Application No. 08/742,255, which was filed on October 31, 1996. Because the '540 patent was filed on March 14, 1997, Applicants respectfully submit that the cited publication is not prior art to the present application, and request that the rejection under 35 U.S.C. §103 be reconsidered and withdrawn.

Obviousness-type double patenting

The Examiner has provisionally rejected claims 1, 2, 5-12, 23, 24, 26-34, and 36-50 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 51, 52, 54, 55, 57-63, 66-68, 70, 71, 73-79, and 82 of copending U.S. Application No. 09/675,518. Applicants respectfully submit that, because the instant claims are in allowable form, the provisional double patenting rejection is the only remaining rejection in the instant application. As such, the examiner should withdraw the rejection and permit the claims to issue. *See, e.g.*, MPEP 804(I)(B).

CONCLUSION

In view of the foregoing remarks, Applicants respectfully submit that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

Respectfully submitted,
FOLEY & LARDNER

Dated: August 22, 2002

By: _____
For Richard J. Warburg,
Michael A. Whittaker
Registration No. 46,230

P.O. Box 80278
San Diego, CA 92138-0278
Voice: 858-847-6700
Fax: 858-792-6773

Appendix A: Marked-up claims, indicating amendments.

1. (Twice Amended) An optical assay device for the detection of an analyte of interest in a sample comprising:

a support containing channels;

an optically functional layer positioned on said support;

an attachment layer positioned on said optically functional layer; and

an analyte specific receptive layer positioned on said attachment layer,

wherein said support and each of said layers are configured and arranged to provide laminar flow of sample flow through each of said layers via said channels of said device [is laminar flow].

2. (Twice Amended) An optical assay device for the detection of an analyte of interest in a sample comprising:

a support containing channels;

an optically functional layer positioned on said support; and

an attachment layer positioned on said optically functional layer,

wherein said support and each of said layers are configured and arranged to provide laminar flow of sample flow through each of said layers via said channels of said device [is laminar flow].

3. (Twice Amended) An optical assay device for the detection of an analyte of interest in a sample comprising:

a porous support;

an optically functional layer comprising discrete, optically functional particles embedded in said support configured and arranged to provide channels through said optically functional layer;

an attachment layer positioned on said particles; and

an analyte specific receptive layer positioned on said attachment layer,

wherein said support and each of said layers are configured and arranged to provide laminar flow of sample flow through each of said layers via said channels of said device [is laminar flow].

4. (Twice Amended) An optical assay device for the detection of an analyte of interest in a sample comprising:

a porous support;

an optically functional layer comprising discrete, optically functional particles embedded in said support configured and arranged to provide channels through said optically functional layer; and

an attachment layer positioned on said particles,

wherein said support and each of said layers are configured and arranged to provide laminar flow of sample flow through each of said layers via said channels of said device [is laminar flow].

5. (Twice Amended) An optical assay device for the detection of an analyte of interest in a sample comprising:

a porous support;

an optically functional layer containing channels positioned on said support;

an attachment layer positioned on said optically functional layer; and

an analyte specific receptive layer positioned on said attachment layer,

wherein said support and each of said layers are configured and arranged to provide laminar flow of sample flow through each of said layers via said channels of said device [is laminar flow].

6. (Twice Amended) An optical assay device for the detection of an analyte of interest in a sample comprising:

a porous support;

an optically functional layer containing channels positioned on said support; and

an attachment layer positioned on said optically functional layer,

wherein said support and each of said layers are configured and arranged to provide laminar flow of sample flow through each of said layers via said channels of said device [is laminar flow].

18. (Third amended) Method for constructing an optical assay device with laminar flow properties, comprising the steps of:

providing a support;

providing an optically functional layer on said support;

providing an attachment layer on said optically functional layer; and

providing an analyte specific receptive layer on said optically functional layer, wherein said support and said layers are configured and arranged to provide laminar flow through each of said layers via said channels or through each of said layers via said channels and across one or more of said layers of said device.

19. (Third amended) Method for constructing an optical assay device with laminar flow properties, comprising the steps of:

providing a support;

providing an optically functional layer on said support; and

providing an attachment layer on said optically functional layer, wherein said support and said layers are configured and arranged to provide laminar flow through each of said layers via said channels or through each of said layers via said channels and across one or more of said layers of said device.

23. (Twice Amended) A composition comprising a support comprising channels, and an optically functional layer configured and arranged to provide laminar flow of sample through said optically functional layer towards said support via said channels.